

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet 1 of 1

Application Number	10/517,122
Filing Date	December 2, 2004
First Named Inventor	JIN, Tuo
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	691-C-PCT(CN)-US

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁸
		<small>Country Code³*Number⁴*Kind Code⁵(if known)</small>				
GK	1	CN1054009A	08-28-1991	Takeda Chemical Ind., Ltd.		

Examiner Signature	G. Kozin	Date Considered	7/20/07
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DT05 [redacted] PCT/PTO 02 DEC 2004

PTO/SB/08A (02-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	Not Yet Known
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Attorney Docket Number	691-C-PCT(CN)-US
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Sheet 1 of 4

U. S. PATENT DOCUMENTS

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Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T*
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
GE	2	WO 96/40071	12-19-1996	Neocrin Company		
GE	27	CN1054009A	08-28-1991	Takeda Chemical Ind., Ltd.		
GE	28	WO 0/041,682 A	07-02-2000	LG Chemical, Ltd.		

**Examiner
Signature**

G. Kozislu

Date	
Considered	

7/20/07

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Sheet	2	of	4

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
GK	4	Langer, R., Folkman, J., "Polymers for the sustained release of proteins and other macromolecules," Nature 263, 797-800 (1976).	
	5	CAS, Results of search on chemical abstracts on the subject of sustained release of proteins based on degradable polymers." (2002).	
	6	Weert, M. v., Hennink, W. E., Jiskoot, W., "Protein instability in poly(lactic-co-glycolic acid) microparticles," Pharm. Res. 17, 1159-1167 (2000).	
	7	Bartus, R. T., Tracy, M.A., Emerich, D.F., Zale, S.E., "Sustained delivery of proteins for novel therapeutic products," Science 281, 1161-1162 (1998).	
	8	Burke, P. A., "Controlled release protein therapeutics: effects of process and formulation on stability," Handbook of pharmaceutical controlled release technology, Marcel Dekker, 661-692 (2000).	
	9	Cleland, J. L., Jones J.S., "Stable formulations of recombinant human growth hormone and interferon- for microencapsulation in biodegradable microspheres," Pharm. Res. 13, 1464-1475 (1996).	
	10	Johnson, O. L., "The stabilization and encapsulation of human growth hormone into biodegradable microspheres," Pharmaceutical Research 14, 730-735 (1997).	
	11	Cunningham, B. C., Mulkerrin, M. G., Wells, J. A., "Dimerization of human growth hormone by zinc," Science 253, 545-548 (1991).	
	12	Sanchez, A., Villamayor, B., Guo, Y., McIver, J., Alonso, M. J., "Formulation strategies for the stabilization of tetanus toxoid in poly(lactide-co-glycolide) microspheres," Intern. J. Pharm. 185, 255-266 (1999).	
GK	13	Schwendeman, S. P., Tobio, M., Jaworowicz, M., Alonso, M. J., Langer, R., "New strategies for the microencapsulation of tetanus vaccine," J. Microencapsulation 15, 299-318 (1998).	

Examiner Signature	<i>G. K. Langer</i>	Date Considered	7/20/07
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		Examiner Name	Not Yet Known
Sheet	3	of	4
		Attorney Docket Number	691-C-PCT(CN)-US

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
GK	14	Morlock, M., Koll, H., Winter, G., Kissel, T., "Microencapsulation of rh-erythropoietin, using biodegradable poly(D,L-lactide-co-glycolide):protein stability and the effects of stabilizing excipients," European Journal of Pharmaceutics and Biopharmaceutics 43, 29-36 (1997).	
	15	Yoshioka, S., Aso, Y., Kojima, S., "Dependence of the molecular mobility and protein stability of freeze-dried -globulin formulations on the molecular weight of dextran," Pharmaceutical Research 14, 736-741 (1997).	
	16	Weert, M. v. d., Hof, R. v., Weerd, J. v. d., Heeren, M.A., Posthuma, G., Hennink, W. E., Crommelin D. J. A., "Lysozyme distribution and conformation in a biodegradable polymer matrix as determined by FTIR techniques," J. Controlled Release 68, 31-40 (2000).	
	17	Morita, T., Horikiri, Y., Suzuki, T., Yoshino, H., "Preparation of gelatin microparticles by co-lyophilization with poly(ethylene glycol): characterization and application to entrapment into biodegradable microspheres," International Journal of Pharmaceutics 219, 127-137 (2001).	
	18	Maa, Y.-F., Nguyen, P.-A., Hsu, S. W., "Spray-drying of air-liquid interface sensitive recombinant human growth hormone," J. Pharm. Sci., 87, 152-159 (1998).	
	19	Morita, T., Horikiri, Y., Yamahara, H., Suzuki, T., Yoshino, H., "Formation and isolation of spherical fine protein microparticles through lyophilization of protein-poly(ethylene glycol) aqueous mixture," Pharm. Res. 17, 1367-1373 (2000).	
	20	Park, T. G., Lee, H.Y., Nam, Y.S., "A new preparation method for protein loaded poly(D,L-lactic-co-glycolic acid) microspheres and protein release mechanism study," J. Controlled Release 55, 181-191 (1998).	
	21	Franssen, O., Hennink, W. E., "A novel preparation method for polymeric microparticles without the use of organic solvents," Intern. J. Pharm., 168, 1-7 (1998).	
	22	Schwandeman, S. P., Cardamone, M., Brandon, M. R., Klibanov, A., Langer, R., "Stability of proteins and their delivery from biodegradable polymer microspheres," S. C. H. Bernstein, Ed., Microparticulate Systems for the Delivery of Proteins and Vaccines, (Merck Dekker, New York, 1996), vol. 77, 1-49.	
GK	23	Liu, W. R., Langer, R., Klibanov, A. M., "Moisture-induced aggregation of lyophilized proteins in the solid state," Biotech. Bioeng. 37, 177-184 (1991).	

Examiner Signature	G. Karzian	Date Considered	7/20/07
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10/517122

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GK	24	Bittner, B., Morlock, M., Koll, H., Winter, G., Kissel, T., "Recombinant human erythropoietin (rhEPO) loaded poly(lactide-co-glycolide) microspheres: influence of the encapsulation technique and polymer purity on microsphere characteristics," Eur. J. Pharm. Biopharm. 45, 295-305 (1998).	
	25	Takahata, H., Lavelle, E.C., Coombes, A.G.A., Davis, S.S., "The distribution of protein associated with poly(DL-lactide co-glycolide) microparticles and its degradation in simulated body fluids," J. Controlled Release 50, 237-246 (1998).	
	26	PCT International Search Report for JIN, et al, Int'l Application No. PCT/CN/00431, Filed June 3, 2003, Dated August 1, 2003.	
GK	29	A. Berthold et al., "Preparation and Characterization of Chitosan Microspheres as Drug Carrier for Prednisolone Sodium Phosphate as Model for Antiinflammatory Drugs", Journal of Controlled Release, 1996,39, 17-25.	

Examiner Signature	G. Karim	Date Considered	7/20/07
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